

REMARKS

Claims 25-48 were rejected. Claims 26-27, 41, 44, and 46-48 are herein cancelled. Claim 25 is herein amended. No new matter is added. Claims 25, 28-40, 42-43, and 45 are now pending. The above amendments and the following remarks are considered by Applicants to overcome each rejection raised by the Examiner and to place the application in condition for allowance.

Rejections of claims 25-48 pursuant to 35 U.S.C. § 101

The Examiner rejected claims 25-48 pursuant to 35 U.S.C. § 101 as being non-statutory subject matter. Applicants respectfully traverse the rejection.

Shortly after the mailing of the current Office Action, the United States Federal Circuit released its much-anticipated decision in *In re Bilski*, 2008 U.S. App. LEXIS 22479 (Fed. Cir. 2008). The decision provides generally that “[a] claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.” *Id.* at 24 (citations omitted).

Regarding transformation, *Bilski* provided that a method is patent-eligible if it transforms data representing physical objects or substances. *Id.* at 50-53. For example, *Bilski* cited *In re Abele*, 684 F.2d 902 (CCPA 1982), for the holding that a method is patent-eligible where it transforms data that “clearly represent[s] physical and tangible objects, namely the structure of bones, organs, and other body tissues.” *Bilski*, 2008 U.S. App. LEXIS at 50. The claimed method in *Bilski* was not patentable subject matter because it “[did] not transform any article to a different state or thing.” Specifically, *Bilski* held: “Purported transformations or manipulations of public or private legal obligations or relationships, business risks, or other such abstractions cannot meet the test because they are not physical objects or substances, *and they are not representative of physical objects or substances.*” *Id.* at 52-53.

By contrast, the claimed method transforms data representative of physical objects. Specifically, the instant application claims a method for spectral photometric determination of the oxygen saturation of the blood in optically accessible blood vessels. The method does not claim a transformation of “public or private legal obligations or relationships, business risks, or other such abstractions.” Rather, the method transforms data representing blood vessels and their vessel-free environment (and the intensity of their reflection) and transforms the data to information regarding the oxygen saturation in the blood. Similar to *Abele*, the claimed method transforms data representing parts of the human body. Accordingly, the claimed method

constitutes patentable subject matter, and therefore Applicants respectfully request withdrawal of the rejection.

Rejections of claims 25-37, 40-41, and 44-48 pursuant to 35 U.S.C. § 102(b)

The Examiner rejected claims 25-37, 40-41, and 44-48 pursuant to 35 U.S.C. § 102(b) as being anticipated by Beach (WO 00/06017). Applicants respectfully traverse the rejection.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicants respectfully submit that Beach does not disclose each element of independent claim 25.

Amended independent claim 25 requires the following step:

illuminating simultaneously the blood vessels and their vessel-free environment *exclusively* by wavelengths used for subsequent data gathering, wherein the wavelengths used for subsequent data gathering consist of at least one measurement wavelength and at least one reference wavelength of an illumination beam for recording spectrally different images

By limiting the illuminating wavelengths to the measurement wavelength and reference wavelength, the present invention can reduce the stress on the patient while recording the spectrally different images, and provide an improved signal-to-noise ratio ([0015] of application). Figure 1 shows this objective achieved by implementing a filter device 3 into the illuminating beam 1 that lets pass only those wavelengths that correspond to the channels of a color camera 4 ([0039] of application). The preferred embodiment of the invention thus reduces the range of wavelengths used for illuminating those spectral portions correlated to the channels of the color camera ([0018] of application). The reduced number of illuminating wavelengths causes an improved signal-to-noise ratio, which allows for discrimination between types of blood vessels by the optical density ratio (“ODR”). The strongly increased sensitivity of the method according to the application allows for referencing and determining the correctives within the particular tissue under study without the need for clinical studies.

Beach does not disclose illuminating simultaneously the blood vessels and their vessel-free environment *exclusively* by the measurement wavelength and reference wavelength. Rather, Beach illuminates the eye by a flash light (30; page 15, line 16 - page 16, line 13), splits the

beam, and filters the reference and measurement wavelengths *after* a first image has been created by the fundus camera 10 (page 5, lines 2-3). Beach's method causes a higher stress to the eye of the patient because illumination occurs with a range of wavelengths of at least 60 nm (page 15, lines 11-13 of Beach). Beach takes some measures to suppress stray light (e.g. page 20, lines 14-20 of Beach), but requires a complex technical arrangement, including mirrors to compensate for lateral displacements of first 13 and second images 17 (e.g. page 18, lines 1-3 of Beach). But Beach does not limit the illuminating light to the measurement wavelength and reference wavelength.

Amended independent claim 25 also requires the following step:

determining the oxygen saturation of the blood from a linear, empirically-determined function between the oxygen saturation and a logarithmized ratio of the intensities of the reflection of the blood vessels and their vessel-free environment at the measurement wavelength and at the isosbestic wavelength, wherein the slope and linear term of the function are determined empirically from readings at a plurality of blood vessels.

Beach also fails to disclose this limitation. The Examiner contends that Beach discloses the determination of the slope and linear term of a linear function for computing oxygen saturation by reading over a plurality of blood vessels. This does not apply as Beach discloses the use of a mean derived from several linear regressions of ODR versus systemic oxygen saturation (Figs. 13, 14 and 16, page 24, lines 24 to page 25, line 12; page 26, lines 20-25 and page 30, lines 12-19 of Beach). In contrast to Beach, the present application uses readings over a plurality of blood vessels in the eye of a particular patient for determination of the terms of the linear function ([0019]). This is an improvement as determination of oxygen saturation can be done specifically to a particular patient, without computing a mean from several individuals in a clinical study.

Regarding dependent claims 28-31, the Examiner contends that Beach discloses "using correctives that are empirically determined, the correctives comprising a linear function of *either* the vessel diameter or pigmentation" (Current Office Action at 3.) Claims 28-31, however, require that "disturbances ... on the vessel diameter *and* on the pigmentation ... are compensated by correctives." Beach discloses correctives for pigmentation, but not for pigmentation *and* vessel diameter (page 33, line 14 to page 41, line 2). Accordingly, Beach also requires that a patient inhale oxygen for examination, and its methods for determining correctives for the linear function are based on external reference data. Gathering statistically sufficient data requires a

large clinical study (page 23, lines 14 - 18). Thus, the quality of the empirical data, and consequently the quality of the measurements taken from a particular patient (because they rely on the empirical data), depend on the structure of the group (number of, individuals, proportion of subjects with low/average/high pigmentation of the eye fundus, age of probands) studied for referencing (page 33, line 7-11). By contrast, the claimed invention gives correctives for *both* the vessel diameter and pigmentation ([0044] to [0047] and equations 2, 3, 4 and 5). The application discloses a method for correction for measurement errors due to individual tissue constitution regarding vessel diameter and pigmentation simultaneously. Inhalation of oxygen by the patient is optional, but not fundamental as in Beach.

Further, dependent claims 32-35 require that the determination of the type of blood vessel (e.g., as an artery or vein) be conducted automatically by the definition of a threshold value derived from reflection ratios ([0022], [0033], [0051], Fig. 3). Beach does not disclose a method or algorithm for automatic discrimination of the types of blood vessels.

Further, dependent claim 36 requires that “specular reflections on the blood vessels are identified and eliminated automatically through image-processing means or manually.” Beach does not disclose a method or algorithm to correct for that source of error.

Finally, dependent claim 45 requires that “systolic and diastolic differences in oxygen saturation are obtained as diagnostic features by recording pulse-synchronized sequences of images.” Beach does not disclose obtaining such differences.

For the foregoing reasons, Applicants respectfully submit that it would not have been obvious to one of ordinary skill in the art to arrive at the invention of independent claim 25 or its dependent claims. Accordingly, Applicants respectfully request withdrawal of the rejection.

Rejections of claims 38-39 and 42-43 pursuant to 35 U.S.C. § 103

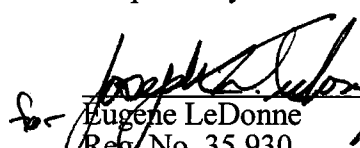
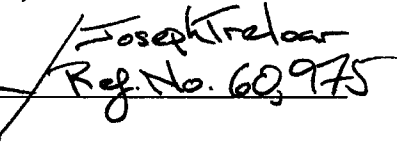
The Examiner rejected claims 38-39 pursuant to 35 U.S.C. § 103 as being unpatentable over Beach as applied to claim 37 in view of Faubert (2001/0056247). Further, the Examiner rejected claims 42-43 pursuant to 35 U.S.C. § 103 as being unpatentable over Beach as applied to claim 25 in view of Cabib (U.S. Pat. No. 6,556,853).

Claims 38-39 and 42-43 depend from independent claim 25. As claim 25 is allowable, so must be claims 38-39 and 42-43. Accordingly, Applicants respectfully request withdrawal of the obviousness rejections.

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An early action on the merits of these claims is respectfully requested.

Respectfully submitted,

 
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